IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LTD. AND SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Plaintiffs,	)	
v.	)	C.A. No. 1:08-cv-00551-JJF
LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.,	)	JURY TRIAL DEMANDED
Defendants.	)	

DEFENDANTS' ANSWER AND COUNTERCLAIMS

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI") (collectively "Defendants") answer the Complaint as follows:

THE PARTIES

1. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1, and therefore deny these allegations.

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2, and therefore deny these allegations.

3. Admitted.

4. Defendants admit that Lupin Ltd., *inter alia*, manufactures quality generic drugs. Defendants deny the remaining allegations of Paragraph 4.

5. Admitted. Further answering, Defendants deny that LPI is a proper party to this action.

6. Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny all allegations of Paragraph 6. Defendants further deny that LPI is a proper party to this action.

7. Denied. Further answering, Defendants deny that LPI is a proper party to this action.

8. Denied.

9. Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit only that LPI is a wholly-owned subsidiary of Lupin Ltd. Defendants deny that LPI is a proper party to this action, and deny all remaining allegations of Paragraph 9.

THE NATURE OF THE ACTION

10. Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that this action purports to allege infringement of U.S. Patent No. 5,859,021 under the patent laws. Defendants deny all remaining allegations of Paragraph 10.

JURISDICTION AND VENUE

11. Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that this Court has subject matter jurisdiction over the claims asserted against Lupin Ltd. only. Defendants deny that subject matter jurisdiction is proper for the claims directed at LPI, and deny that LPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 11.

12. Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, and to conserve the resources of the parties and

the Court, Defendants do not contest personal jurisdiction for the purpose of this action only. Defendants deny that LPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 12.

13. Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, and to conserve the resources of the parties and the Court, Defendants do not contest venue for the purpose of this action only. Defendants deny that LPI is a proper party to this action. Defendants deny all remaining allegations of Paragraph 13.

THE PATENT

14. Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, according to the records of the United States Patent and Trademark Office ("PTO"), Defendants admit that the PTO issued the '021 patent, entitled "Antiviral Combinations," on or about January 12, 1999; that the cover page of the '021 patent identifies Glaxo Group Limited (Greenford, United Kingdom) as assignee; and that what purports to be a copy of the '021 patent is attached to the complaint as Exhibit A. Defendants deny that the '021 patent was "duly and legally issued," and deny all remaining allegations of Paragraph 14.

ACTS GIVING RISE TO THIS ACTION

15. Defendants admit that, according to the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), FDA approved New Drug Application ("NDA") No. 20-857 for COMBIVIR® (lamivudine/zidovudine) Tablets 150 mg/ 300 mg on or about September 26, 1997; and that the electronic version of FDA's Orange Book

identifies "GlaxoSmithKline" as the "applicant" for NDA No. 20-857. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 15, and therefore deny these allegations.

16. Defendants admit that Lupin Ltd. has submitted an Abbreviated New Drug Application ("ANDA") to FDA for Lamivudine and Zidovudine Tablets 150 mg/300 mg. Defendants deny all remaining allegations of Paragraph 16, and deny that LPI is a proper party to this action.

17. Defendants admit that Lupin Ltd.'s ANDA seeks FDA approval to engage in the commercial manufacture, use and sale of Lamivudine and Zidovudine Tablets 150 mg/300 mg before the expiration of the '021 patent. Defendants deny all remaining allegations of Paragraph 17.

18. Defendants admit that Lupin Ltd.'s ANDA for Lamivudine and Zidovudine Tablets 150 mg/300 mg contains a so-called "paragraph IV certification" stating that the '021 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Lupin Ltd.'s ANDA; and that, on July 16, 2008, Lupin Ltd. provided the requisite and timely notice of its ANDA and paragraph IV certification to GlaxoSmithKline and Glaxo Group Limited. Defendants deny all remaining allegations of Paragraph 18.

19. Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny all allegations of Paragraph 19. Defendants further deny that LPI is a proper party to this action.

20. Denied.

21. Denied.

22. Denied.

23. Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that Lupin Ltd. was aware of the '021 patent prior to submitting its ANDA. Defendants deny all remaining allegations of Paragraph 23. Defendants further deny that LPI is a proper party to this action.

24. Denied.

* * *

Defendants deny all allegations not expressly admitted or responded to herein. Defendants further deny that GSK is entitled to any of the relief requested, or to any relief at all, and respectfully pray that the Court enter judgment for Defendants, dismissing this action with prejudice, and awarding Defendants their attorneys' fees and costs of this action pursuant to 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation of the Complaint not otherwise admitted, and without assuming any of the burdens imposed by law on any of the Plaintiffs, Defendants assert the following separate defenses:

First Defense

The manufacture, use, sale, offer for sale, or importation of the drug product subject to Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not – if marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of U.S. Patent No. 5,859,021 ("'021 patent"), either literally or under the doctrine of equivalents.

Second Defense

Defendants have not induced, do not induce, and will not induce infringement of any valid and/or enforceable claim of the '021 patent.

Third Defense

Defendants have not contributed, do not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '021 patent.

Fourth Defense

The claims of the '021 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Fifth Defense

The Court lacks subject matter jurisdiction over any claims asserted against LPI.

Sixth Defense

LPI is not a proper party to this action.

Seventh Defense

The complaint fails to state a claim upon which relief may be granted.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Lupin Ltd. asserts the following counterclaims against Plaintiffs/Counterclaim-Defendants Glaxo Group Ltd. and SmithKline Beecham Corporation (d/b/a GlaxoSmithKline):

Parties

1. Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at Laxmi Towers "B" Wing, 5th floor, Banda Kurla Complex, Mumbai 400 051, India.

2. Glaxo Group Limited purports to be a company organized and existing under the laws of England and having an office and place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB60NN, United Kingdom.

3. SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, purports to be a Pennsylvania corporation having an office and place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Lupin Ltd. in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Patent-in-Suit

8. On or about January 12, 1999, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,859,021 ("the '021 patent"), entitled "Antiviral Combinations," to Janet Mary Cameron and Nicholas Cammack.

9. On or about May 18, 1999, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,905,082 ("the '082 patent"), entitled "Crystalline Oxathiolane Derivatives," to Tony Gordon Roberts and Paul Evans.

10. Plaintiffs/Counterclaim-Defendants purport and claim to own, and have the right to enforce, the '021 and '082 patents.

11. Plaintiffs/Counterclaim-Defendants submitted the '021 and '082 patents to the FDA for listing in the Orange Book in connection with NDA No. 20-857 for COMBIVIR® (lamivudine/zidovudine) Tablets 150 mg/300 mg.

12. Lupin Ltd. submitted an ANDA to the FDA containing a paragraph IV certification to the '021 and '082 patents.

13. On August 29, 2008, Plaintiffs/Counterclaim-Defendants sued Lupin Ltd. in this District alleging infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

Count I
(Declaratory Judgment of Non-Infringement of the '021 Patent)

14. Lupin Ltd. re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

15. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Ltd. and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '021 patent.

16. The manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '021 patent, either directly or indirectly.

17. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '021 patent, either directly or indirectly.

Count II
(Declaratory Judgment of Invalidity of the '021 Patent)

18. Lupin Ltd. re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin Ltd. and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '021 patent.

20. The claims of the '021 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

21. Lupin Ltd. is entitled to a judicial declaration that the claims of the '021 patent are invalid.

Count III
(Declaratory Judgment of Non-Infringement of the '082 Patent)

22. Lupin Ltd. re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

23. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Ltd. and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '082 patent.

24. The manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '082 patent, either directly or indirectly.

25. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '082 patent, either directly or indirectly.

Count IV
(Declaratory Judgment of Invalidity of the '082 Patent)

26. Lupin Ltd. re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin Ltd. and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '082 patent.

28. The claims of the '082 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

29. Lupin Ltd. is entitled to a judicial declaration that the claims of the '082 patent are invalid.

Prayer for Relief

WHEREFORE, Lupin Ltd. respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '021 patent, either directly or indirectly;

(b) Declaring that the claims of the '021 patent are invalid;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '082 patent, either directly or indirectly;

(d) Declaring that the claims of the '082 patent are invalid;

(e) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Lupin Ltd.;

(f) Awarding Lupin Ltd. its costs;

(g) Declaring this case exceptional and awarding Lupin Ltd. its reasonable attorneys' fees and costs under 35 U.S.C. § 285;

(h) Awarding Lupin Ltd. such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lupin Ltd. and LPI hereby demand a trial by jury as to all issues so triable.

Dated: October 15, 2008.

Respectfully submitted,

PHILLIPS GOLDMAN & SPENCE, P.A.

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